IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNDER SEAL A & B	§	CIVIL NO. H 07-2953
	§	
	§	
Plaintiffs,	§	**FILED IN CAMERA**
	§	**AND**
v.	§	**UNDER SEAL**
	§	
UNDER SEAL C, D, & E	§	
	§	PLAINTIFFS' ORIGINAL
	§	COMPLAINT PURSUANT TO,
	§	31U.S.C. §§ 3729-3732,
	§	FEDERAL FALSE CLAIMS ACT
	§	
Defendants.	§	
	§	
	§	
	§	
	§	**JURY TRIAL DEMAND**
	§	

PLAINTIFFS' ORIGINAL COMPLAINT

FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA	§	
ex rel. James Banigan and Richard Templin	§	
	§	
STATE OF CALIFORNIA, *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF DELAWARE, *ex rel.*	§	
James Banigan and Richard Templin;	§	
DISTRICT OF COLUMBIA *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF FLORIDA *ex rel.*	§	CIVIL NO. _____
James Banigan and Richard Templin;	§	
STATE OF GEORGIA *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF HAWAII *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF ILLINOIS *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF INDIANA *ex rel.*	§	
James Banigan and Richard Templin;	§	**FILED IN CAMERA AND**
STATE OF LOUISIANA *ex rel.*	§	**UNDER SEAL**
James Banigan and Richard Templin;	§	
COMMONWEALTH OF MASSACHUSETTS	§	
ex rel. James Banigan and Richard Templin;	§	
STATE OF MICHIGAN *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF MONTANA *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF NEVADA *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF NEW HAMPSHIRE *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF NEW MEXICO *ex rel.*	§	JURY TRIAL DEMANDED
James Banigan and Richard Templin;	§	
STATE OF NEW YORK *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF OKLAHOMA *ex rel.*	§	
James Banigan and Richard Templin;	§	
STATE OF TENNESSEE *ex rel.*	§	
James Banigan and Richard Templin;	§	

STATE OF TEXAS *ex rel.* James Banigan and Richard Templin; STATE OF VIRGINIA *ex rel.* James Banigan and Richard Templin;	§
Plaintiffs,	§
VS.	§
ORGANON USA INC.; OMNICARE, INC.; and PHARMERICA, INC.	§
Defendants.	§

ORIGINAL COMPLAINT OF RELATORS JAMES BANIGAN AND RICHARD TEMPLIN PURSUANT TO FEDERAL FALSE CLAIMS ACT, AND VARIOUS STATE FALSE CLAIMS ACTS

1. The United States of America, the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Mexico, New York, Oklahoma, Tennessee, Texas, and Virginia, the Commonwealth of Massachusetts, and the District of Columbia, by and through *qui tam* relators James Banigan and Richard Templin, bring this action under 31 U.S.C. §§ 3729–3732 (the "False Claims Act") to recover all damages, penalties and other remedies established by the False Claims Act on behalf of the United States and themselves and would show the following:

I. PARTIES

2. Relator James Banigan is a citizen of the United States and a resident of the State of New Jersey.

3. Relator Richard Templin is a citizen of the United States and a resident of the State of New Jersey.

4. Defendant Organon USA Inc. ("Organon") is a New Jersey corporation whose principal business is the development, manufacture, and sale of health care products and services, including pharmaceuticals. Organon's principal place of business is at 375 Mount Pleasant Avenue, West Orange, New Jersey 07052. Organon conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Mexico, New York, Oklahoma, Tennessee, Texas and Virginia, the Commonwealth of Massachusetts, and the District of Columbia. Organon is a wholly owned U.S. subsidiary of Akzo Nobel, a Netherlands corporation. Organon manufactures and sells prescription drugs with false and inflated AWPs that are paid for by state Medicaid programs, including such medications as Remeron Tablet and Remeron SolTab.

5. Defendant Omnicare, Inc. is a Delaware corporation whose principal business is providing pharmacy services to patients in long-term care settings. Omnicare's principal place of business is 100 East RiverCenter Boulevard, Covington, Kentucky 41011. Omnicare conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Mexico, New York, Oklahoma, Tennessee, Texas, and Virginia, the Commonwealth of Massachusetts, and the District of Columbia.

6. Defendant PharMerica, Inc. is a Delaware corporation whose principal business is providing pharmacy services to patients in long-term care settings. PharMerica's principal place of business is at 1901 Campus Place, Louisville, Kentucky 40299. PharMerica conducts extensive business in the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Mexico, New York, Oklahoma, Tennessee, Texas, and Virginia, the Commonwealth of Massachusetts, and the

District of Columbia. PharMerica became a wholly-owned subsidiary of Bergen Brunswig, after which Bergen Brunswig merged with AmeriSource Health Corporation on March 29, 2001 to form AmerisourceBergen. In 2006, AmerisourceBergen merged PharMerica with Kindred Healthcare Inc. to form PharMerica Long-Term Care.

II. JURISDICTION AND VENUE

7. Jurisdiction and venue are proper in this Court for the following reasons:

i. Jurisdiction for this Court exists pursuant to the False Claims Act (31 U.S.C. § 3730(b) (1) and 31 U.S.C. § 3732(a)) because Relators' claims seek remedies on behalf of the United States for Defendant's multiple violations of 31 U.S.C. § 3729, some of which occurred in the Southern District of Texas, and because Defendant transacts other business within the Southern District of Texas.

ii. Venue exists in the United States District Court for the Southern District of Texas pursuant to 31 U.S.C. § 3730(b) (1) and 31 U.S.C. § 3732(a) because Defendant is qualified to do business in the State of Texas and conducts business within the State of Texas and within the Southern District and Defendant transacts business or committed acts proscribed by § 3729, in the State of Texas and the Southern District of Texas.

III. INTRODUCTION

8. This suit concerns pharmaceutical company Organon's seven-year scheme to offer unlawful enticements to long-term care pharmacies in exchange for prescribing its anti-depressants, Remeron Tablet and Remeron SolTab, to their patients, resulting in at least $348 million in wrongful Medicaid prescription reimbursement costs. Organon took advantage of the fact that nursing homes and other long-term care facilities nationwide are serviced by a handful of giant, closed-door, specialized long-term care pharmacies such as PharMerica and Omnicare. These pharmacies are uniquely able to influence or control what medications are prescribed to a

patient. Beginning in 1999 and lasting through 2005, Organon secretly offered these pharmacies and their buying groups deep discounts of up to almost 23.5% and other inducements in exchange for converting patients' prescriptions to Remeron Tablet and Remeron SolTab. All of these inducements were offered at Medicaid's expense and constituted kickbacks under federal law.

9. Following Remeron Tablet' patent expiration in 1998, Organon anticipated that generic competition, set to begin in 2001, could cause the company a catastrophic loss of profits. In the face of that threat, Organon sought approval from the Food and Drug Administration (the "FDA") for a variant form of Remeron—an orally disintegrating tablet called Remeron SolTab—that was not rated AB equivalent to Remeron Tablet, effectively barring generic competition for the variant form.

10. Organon then engaged in a fraudulent scheme with long-term care pharmacy providers and group purchasing organizations to exploit the Medicaid reimbursement system by maximizing Medicaid reimbursement to pharmacies while minimizing the price pharmacies actually paid for the drugs. Organon's average wholesale price for Remeron Tablet was already inflated, but beginning in 1999, Organon offered long-term care pharmacies deep discounts and rebates in conjunction with that price to increase the "spread" for the drug further. Upon Remeron SolTab's launch in 2001, Organon set an even higher average wholesale price for the new form and began shifting the discounts and rebates to Remeron SolTab to encourage pharmacies to convert from Remeron Tablet to the patent-protected Remeron SolTab. Organon then conspired with long-term care providers, including Omnicare and PharMerica, as well as group purchasing organizations, by entering into long-term contracts that provided explicitly for these illegal discounts and rebates, such as ramp-up discounts, rebates, conversion rebates, and

therapeutic interchange rebates. These inducements constitute illegal kickbacks under the Medicare and Medicaid Protection Act of 1987 (the "Anti-Kickback Statute"). See 42 U.S.C. § 1320a-7b.

11. Remeron's active ingredient, mirtazapine, is a noradrenergic and selective serotonergic anti-depressant with common side effects of somnolence and weight gain. Organon's sales pitch to long-term care pharmacies simply appealed to pharmacies' "opportunity to profit" on Medicaid prescriptions. But Organon also specifically trained long-term pharmacies to maximize conversion of residents' anti-depressant prescriptions to Remeron by actually promoting Remeron's "fat and sleepy" profile to long-term care facilities, promising a more docile, easily controlled resident population.

12. Organon's appeal to pharmacies to convert patients to Remeron Tablet and especially Remeron SolTab was spectacularly successful. Remeron was Organon's top selling drug from 1999 to 2005. Remeron sales from 1999 to 2004 totaled an estimated $693 million in Medicaid sales, with $347.5 million in long-term care sales. In 2005, Organon's Remeron Medicaid sales totaled about $13 million.

13. Further, by engaging in this scheme to defraud Medicaid with long-term pharmacy providers, such as PharMerica and Omnicare, as well as group purchasing organizations, Organon effectively reduced its liability for Remeron Tablet and Remeron SolTab under its rebate agreement with Medicaid. When calculating its average manufacturer price, Organon included the *deeply discounted* for Remeron Tablet and Remeron SolTab to long-term care customers, even though the discounts constituted illegal kickbacks, decreasing its rebate liability to Medicaid accordingly.

14. Not only did Organon claim reductions to its rebate liability based on illegal kickbacks, but it falsely reported pricing for a number of long-term care transactions involving Remeron Tablet and Remeron SolTab, further lowering the rebate it paid to state Medicaid programs. For example, Organon on two occasions sold a high volume of Remeron SolTab to Omnicare and PharMerica at "bargain basement" prices in exchange for the purchase of more Remeron SolTab at normal commercial prices without reporting these transactions together to Medicaid, thereby lowering the Organon's rebate liability to state Medicaid programs.

15. Organon's marketing of potential profits violated the False Claims Act for two reasons. First, long-term care pharmacy providers impliedly certify when they submit reimbursement requests for Remeron Tablet and Remeron SolTab that they have followed all laws applicable to federal and state healthcare programs. Organon induced these providers to violate the Anti-Kickback Statute, causing these providers' certifications to be false. Second, Organon itself falsely certified compliance with all laws applicable to these programs—an implied certification that Organon made as a condition to participation in the drug formularies of state Medicaid programs—when in fact the claims arose out of violations of the Anti-Kickback Statute.

16. Further, Organon, PharMerica, Omnicare, and other long-term care pharmacy providers violated the False Claims Act by conspiring to obtain payment for claims submitted for reimbursement for illegally-obtained prescriptions for Remeron Tablet and Remeron SolTab.

17. Finally, Organon violated the False Claims Act by making false statements and/or records that led to a decrease in its obligation under state Medicaid rebate programs. Organon used its fraudulent, financial incentives, such as discounts and rebates, to its long-term care pharmacy provider customers to lower the average manufacturer prices for Remeron Tablet and

Remeron SolTab that Organon reported to Medicaid. In addition, Organon avoided disclosing its true best price for Remeron SolTab products. These acts had the effect of lowering Organon's Medicaid rebate liability for Remeron Tablet and Remeron SolTab.

IV. LAW

A. The False Claims Act

18. The False Claims Act ("FCA") provides in pertinent part that:

(a) Any person who

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> ***
> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim. 31 U.S.C. § 3729(a).

B. The Federal Anti-Kickback Statute

19. The Medicare-Medicaid Anti-Fraud and Abuse Amendments, known as the Medicare Anti-Kickback Statute (the "Anti-Kickback Statute"), 42 U.S.C. § 1320a-7b(b), make it illegal for an individual knowingly and willfully to offer or pay remuneration in cash or in kind to induce a physician to order a good or service that is reimbursed by a federal healthcare

program. *See* 42 U.S.C. § 1320a-7b(b)(2). "Remuneration" is broadly defined to include anything of value offered or paid in return for purchasing, ordering, or recommending the purchase or order of any item reimbursable by a federal healthcare program.

20. The purpose of the Anti-Kickback Statute is to prohibit such remuneration in order to secure proper medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services.

21. Paying kickbacks taints an entire prescription, regardless of the medical propriety of its use. The kickback inherently interferes with the doctor-patient relationship and creates a conflict of interest, potentially putting the patient's health at risk.

C. The Medicaid Program

22. Medicaid was established by Title XIX of the Federal Social Security Act, 42 U.S.C. § 1396 *et seq.* (the "Medicaid Program"). Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled.

23. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. *See* 42 U.S.C. § 1396a. The federal portion of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50%, and as high as 83%.

24. The vast majority of states award contracts to private companies to evaluate and process Medicaid recipients' claims for payment. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid program, which in turn obtains federal funds from the United States.

V. FACTUAL ALLEGATIONS

A. Organon and Its Long-Term Care Customers

i. Organon

25. Organon USA Inc. ("Organon") is a pharmaceutical company headquartered in Roseland, New Jersey that manufactures and markets pharmaceuticals for human use. Its core therapeutic fields are reproductive medicine, contraception, anesthesia, and psychiatry. Organon is wholly owned by Organon BioSciences N.V. (OBS), which is in turn wholly owned by Akzo Nobel, a Netherland corporation specializing in chemical coatings. Akzo Nobel announced on March 12, 2007 its intent to sell OBS to pharmaceutical company Schering-Plough for EUR 11 billion. The sale is expected to close on October 1, 2007.

ii. PharMerica

26. In 1999, PharMerica was one of the nation's largest long-term care pharmacy providers, specializing in the provision of pharmacy supplies and services to long-term care institutions. It provided pharmacy products and services to approximately 500,000 patients in long-term care and alternative settings, servicing an estimated 380,000 beds in skilled nursing facilities. On April 26, 1999, Bergen Brunswig acquired PharMerica, Inc. and PharMerica became a wholly-owned subsidiary of Bergen Brunswig. Bergen Brunswig then merged with AmeriSource Health Corporation on March 29, 2001 to form AmerisourceBergen. In 2006, AmerisourceBergen merged PharMerica with Kindred Healthcare Inc. to form PharMerica Long-Term Care, now headquartered in Louisville, Kentucky, allowing PharMerica to better compete with the nation's current giant of long-term care pharmacy services, Omnicare.

iii. Omnicare

27. From 2001 to 2005, Omnicare, headquartered in Covington, Kentucky, systematically acquired its competitor long-term care pharmacy providers, NeighborCare, NCS Healthcare, and American Pharmaceutical Services ("APS"), a subsidiary of Mariner Health Group, making it the nation's largest provider of pharmacy services to long-term care facilities, providing pharmacy services to an estimated 1,400,000 beds in long-term care facilities and other chronic care settings. Omnicare acquired American Pharmaceutical Services from Mariner in 2002, NCS Healthcare in 2003, and NeighborCare, Inc. in 2005.

B. Remeron: Regulatory History and Medical Attributes

28. Organon launched Remeron Tablet in August of 1996 following FDA approval of the drug for the treatment of depression in adults. The drug was billed as the first in a new class of anti-depressants called "noradrenergic and selective serotonergic anti-depressants" ("NaSA"). Remeron Tablet were manufactured in 15 mg, 30 mg, and 45 mg formulations, taken once a day.

29. According to Organon's literature, Remeron has a dual-action effect that rectifies an imbalance of the brain chemicals noradrenaline and serotonin, both of which are believed to be involved in causing depression. Remeron is believed to exert its therapeutic effects by increasing the release of both of these neurotransmitters from nerve cells in the brain, thereby correcting the deficiencies and relieving depressive symptoms such as depressed mood.

30. Organon's patent for Remeron, first issued in 1977, expired on June 14, 1998, with generic manufacturers expected to enter the market as early as May 2001. Organon's managers saw the expiration of Remeron's patent as a potentially cataclysmic event for the company, likely resulting in significant layoffs. Organon undertook three actions to prevent the perceived disaster. First, on November 2, 1999, Organon obtained a new patent that purported to

claim a combination therapy of mirtazapine together with a selective serotonin reuptake inhibitor ("SSRI"), which effectively blocked generic competitors' entry to the marketplace until February of 2003. A patent infringement suit and a related case against Organon brought by generic manufacturers ensued, with the latter case finally settling in August of 2005.

31. Second, Organon submitted a new drug application to the FDA for a variant form of Remeron: an orally disintegrating tablet called Remeron SolTab, available in the same dosages as the tablets. Organon trumpeted Remeron SolTab as improving "patient compliance," particularly in long-term care, because it could be administered without water. The FDA approved the new Remeron product on January 12, 2001. Because Remeron SolTab was not rated as AB equivalent to Remeron Tablet, generic competitors were barred from manufacturing a similar mirtazapine orally-disintegrating tablet.

32. Finally, in late 1999, Organon began implementing a scheme to defraud Medicaid. Specifically, Organon began marketing to long-term care pharmacies the "opportunity to profit" from Remeron prescriptions under Medicaid, urging these customers to take advantage of a sizable "spread" between the discounted price to pharmacies and the much higher reimbursement to be received by Medicaid. Long-term sales increased steadily with the implementation of this scheme, making Remeron Organon's single largest-selling product even before 2001. In 2001, Organon began to focus on converting Remeron Tablet sales to Remeron SolTab, its patent-protected product, and at that time, the company actually documented its scheme in marketing materials distributed to long-term care pharmacies.

33. Organon's Medicaid scheme was extremely successful. Remeron was Organon's top selling drug from 1999 to 2005. Remeron sales from 1999 to 2004 totaled an estimated $693

million in Medicaid sales, with $347.5 million in long-term care sales. In 2005, Organon's Remeron Medicaid sales totaled about $13 million.

C. Remeron Sales to Long-Term Care

34. Remeron has never been among those anti-depressants that have attained "household name" status such as Prozac, Paxil, or Zoloft. Its selling points—a short half-life and claims of avoidance of side effects such as insomnia and anxiety—had apparently not proved compelling enough to health care providers at large. Indeed, two of Remeron's most common side effects, somnolence and weight gain, are particularly troublesome for many depression sufferers. Remeron, however, has had one, very lucrative niche: *long-term care*. While Remeron products made up only 5% of the overall market share for anti-depressants during the relevant period, they made up 15% percent of anti-depressant sales to long-term care pharmacies—a three-fold increase in market share. From 2000 to 2004, nearly 19% of Remeron's total sales derived from prescriptions for residents of long-term care facilities. These pharmacies had powerful financial reasons to prefer Remeron, as described below.

i. Pharmaceutical Sales in the Long-Term Care Arena: The Players and the Structures of Sales

35. As Organon noted in its Sales Training Manual for Long Term Care ("LTC Sales Manual"), the senior care marketplace is the fastest-growing segment of the healthcare industry for pharmaceutical sales, as the growing elderly population has created a rapidly rising demand for long-term care services.

36. Most "skilled nursing facilities," or nursing homes, contract with "long-term care pharmacy providers" ("LTCPPs"),[1] which are institutional pharmacies specializing in the skilled

[1] Organon refers to long term care pharmacies such as PharMerica as "pharmacy providers," and thus uses the acronym "LTCPP," but they are also known as "LTCPs," long term care pharmacies.

nursing facility ("SNF") market. Some nursing homes have their own in-house pharmacies, while many others contract with nationwide corporate pharmacy providers. In 1999, as Organon's LTC Sales Manual explained, the top five corporate long-term care pharmacy providers accounted for over 50% of all U.S. nursing home residents:

Company	**Number of SNF Beds Serviced**
Omnicare	578,000
PharMerica	380,000
NeighborCare	248,000
NCS	248,000
Living Centers of America	101,000

37. By 2001, according to a Remeron business plan authored by Organon managers John Maddox and Butch McKenna ("Business Plan"), the seven largest LTCPPs accounted for almost 77% of skilled nursing facilities and 72% of total skilled nursing facility beds:

LTCPP	**# SNFs**	**# Beds**	**# SNFs**	**# Beds**	**% SNFs**	**% Beds**
NeighborCare	2,100	211,500	17,176	1,848,293	12.2%	11.4%
PharMerica	2,850	287,760	17,176	1,848,293	16.6%	15.6%
Omnicare	5,000	495,000	17,176	1,848,293	29.1%	26.8%
NCS	1,875	188,100	17,176	1,848,293	10.9%	10.2%
APS	430	50,000	17,176	1,848,293	2.5%	2.7%
Vencare	325	32,000	17,176	1,848,293	1.9%	1.7%
Sunscript	600	56,800	17,176	1,848,293	3.5%	3.1%
TOTAL	**13,180**	**1,321,160**	**17,176**	**1,848,293**	**76.7%**	**71.5%**

38. In order to buy the drug they disburse to residents, long-term care pharmacies generally contract with one of the following: (1) a long-term care buying group; (2) a group purchasing organization ("GPO"); or (3) the pharmaceutical company itself. Among the most prominent GPOs are Managed Healthcare Associates, Inc. ("MHA"), based in East Hanover, New Jersey, GeriMed, based in Louisville, Kentucky, and Committed Provider Services, an alliance between Bergen Brunswig Drug Company, NCS Healthcare, and Tenet BuyPower.

Together, in 2001, these GPOs represented over 90% of Remeron Tablet and Remeron SolTab prescriptions filled in long-term care.

39. Long-term care pharmacies wield a powerful influence over the choice of drugs used in long-term care facilities. Upon entering a nursing home, a resident generally severs his or her ties to a family physician and falls under the care of a physician responsible for the particular facility, who generally visits the facility every thirty days. Nurses and other facility staff who see the patient daily become the physician's influential "eyes and ears," in close consultation with the pharmacy's consultant pharmacist and clinical pharmacy staff. Long-term care pharmacies in turn can implement formularies and "therapeutic interchange programs" to attempt to convert prescriptions to a preferred drug. In its LTC Sales Manual, Organon instructed its LTC sales force that long-term care pharmacy providers working through contracted GPOs set up such therapeutic interchange and switch programs "in an effort to contain costs and maximize profits."

40. Because long-term care pharmacy providers and GPOs could exert considerable control over the drugs prescribed to nursing home residents, Organon, in marketing drugs in the long-term care arena from 1999 to at least 2004, focused *not on physicians*, but on "key decision-makers" within the long-term care pharmacy providers, such as their regionally-based clinical staff, consultant pharmacists, Directors of Pharmacy Operations, or Purchasing Directors.

41. Organon put it this way in its LTC Sales Manual:

> Field sales personnel have traditionally focused primarily on direct physician interaction. Now, successful sales calls in the long-term care market include other important decision-makers who may influence physician prescribing practices. These include pharmacy provider personnel, consultant pharmacists, nurses, medical directors, and SNF administrators. Your knowledge of the long-term care market and the roles and responsibilities of key decision-makers will give you a competitive advantage.

What pharmacy providers care about, Organon assured its sales force, was a pharmaceutical product's "spread," and its effect on "maximiz[ing] profit." LTC Sales Manual. The "spread" is the difference between the actual selling price and the reimbursement from the state Medicaid programs. "Spread may be a critical component in selecting preferred products within a therapeutic category," Organon noted in its LTC Sales Manual.

42. Beginning in 1999, Organon entrusted the marketing of this spread—and the negotiation of long-term contracts with long-term care pharmacy providers—not to its normal sales force of about 500 Remeron sales representatives, but to a special, more discreet group of about twenty regional account managers specializing in long-term care, called Long Term Care Sales Specialists. In fact, normal field representatives did not call on long-term facilities at all.

43. Long-term contracts arising out of this specialized sales force's calls were approved by a contract review committee, which was headed up by the Vice President of Marketing and the Executive Director of Managed Markets, both of whom were members of Organon's Executive Leadership Team.

ii. Long-Term Care Is Dominated by Medicaid, and Organon's Contracts with Long-Term Care Pharmacy Providers and GPOs Reflected Medicaid Pricing.

44. Long-term care residents often arrive at a nursing home with Medicare coverage, but Medicare provides only a limited number of days of coverage. Once those days are exhausted and the resident meets the required income level by depleting his or her savings, that resident becomes eligible for Medicaid, with its accompanying prescription benefit. In the 1999 to 2005 time period, according to Organon, about 86% of nursing home residents were Medicaid-eligible, including those eligible under both Medicare and Medicaid. In contrast,

managed care and cash reimbursement in 1997 comprised only 14% of total long-term care revenue.

45. Medicaid thus dominated the long-term care segment of pharmaceutical sales until Medicare Part D commenced in January of 2006. Exploiting Medicaid reimbursement rules played a central role in how Organon did business in that arena. Specifically, as described in more detail below, from 1999 to at least 2005, Organon offered significant rebates, coupled with an inflated Average Wholesale Price ("AWP") for Remeron Tablet and Remeron SolTab in order to create additional profit for pharmacies prescribing Remeron Tablet and Remeron SolTab. AWP is the price at which a pharmaceutical manufacturer or a wholesaler typically sells a drug to a retail customer. Organon then marketed that spread to large corporate long-term care pharmacy providers and buying groups and entered long-term contracts providing specifically for those discounts, rebates, and other financial incentives, often in exchange for bestowing Remeron Tablet and Remeron SolTab with a "preferred" status. All of these spread enhancements were done at Medicaid's expense.

46. Relators' evidence of this Medicaid scheme is abundant: Organon compiled a notebook entitled "Remeron SolTab Therapeutic Interchange Toolkit," accompanied by branded electronic interactive financial modeling tools meant to describe to the long-term care pharmacy providers how they could enrich themselves by increasing the number of Remeron scripts they filled. That notebook is described in more detail below.

D. Drug Reimbursement Under State Medicaid Programs

i. Purpose of National Drug Codes

47. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–97, requires pharmaceutical companies to submit to the Food and Drug Administration ("FDA") a listing of

every drug product in commercial distribution. 21 U.S.C. § 355. The FDA assigns each listed drug product a unique 11-digit, 3-segment number, known as the National Drug Code ("NDC"). The FDA has assigned approximately 170,000 NDCs to drug products. The drugs and corresponding NDCs at issue in this case are listed below:

DRUG	**NDC #**
Remeron Tablet, 15 mg	00052-0105
Remeron Tablet, 30 mg	00052-0107
Remeron Tablet, 45 mg	00052-0109
Remeron SolTab, 15 mg	00052-0106
Remeron SolTab, 30 mg	00052-0108
Remeron SolTab, 45 mg	00052-0110

48. Drug manufacturers such as Organon do not typically submit Medicaid claims themselves. Instead, Organon markets its products to long-term care pharmacy providers, who then purchase the product either directly or through long-term care buying groups or GPOs. These long-term care pharmacy providers then submit claims for payment to Medicaid after dispensing or administering Remeron Tablet and Remeron SolTab. For the most part in the Medicaid program, claims submitted by providers are processed and tracked using the NDC of the drug.

ii. Medicaid Reimbursement Formulas

49. Reimbursement for drugs under state Medicaid programs depends in part on whether the drug is a single source or multiple source drug. A single source drug means a drug that is produced or distributed under an original new drug application approved by the FDA. 42 U.S.C. § 1396r-8(k)(7)(iv). A multiple source or multi-source drug is one for which there is at least one other drug product that is rated therapeutically equivalent or pharmaceutically equivalent and bioequivalent under FDA standards and is sold or marketed in the states. 42 U.S.C. § 1396r-8(k)(i).

50. When reimbursing for drugs, the state Medicaid programs' goal has been to pay an amount which, in the aggregate, reflects the lower of: (1) the estimated acquisition cost ("EAC") of covered drugs, plus a reasonable dispensing fee; or (2) a provider's usual and customary charge to the general public. To determine the EAC for a covered drug, state Medicaid programs are required to develop reimbursement formulas that must be approved by the Secretary of Health and Human Services ("HHS"). 42 C.F.R. §§ 447.331, 447.332, 447.333 (2005).

51. While specific reimbursement formulas vary from state to state, the various state Medicaid programs generally have reimbursed for each drug based on the lowest of: (a) the EAC as set by the states; (b) the maximum allowable cost ("MAC") set by the state Pharmaceutical Boards of the Federal Upper Limit ("FUL") set by the federal government; or (c) the providers' usual and customary charge. For multiple source drugs subject to a federal upper limit, states must, in the aggregate, not pay more than those limits. 42 C.F.R. §§ 447.331, 447.332, 447.333 (2005).

a. States' Methods for Calculating Estimated Acquisition Cost

52. The states' various methodologies for arriving at EAC include:

(a) discounting a percentage off of the Average Wholesale Price ("AWP");

(b) adding a percentage to the Wholesale Acquisition Cost ("WAC"); and/or

(c) requiring the drug companies to certify prices directly in writing to the Medicaid program in response to state requests for particular pricing information.

53. AWP is used to refer to the price at which a pharmaceutical manufacturer or a wholesaler typically sells a drug to a retail customer, who then administers it to a patient. WAC

is used to refer to the price at which a pharmaceutical manufacturer typically sells a drug to wholesalers, who then resell it to a retail customer.

54. While the majority of states use published AWPs to calculate reimbursement, nine states (Alabama, Arkansas, Colorado, Florida, Maryland, Massachusetts, Ohio, Rhode Island, and Texas) use the wholesale acquisition cost ("WAC") to set the EAC.

55. The AWPs and WACs relied upon by the state Medicaid programs are published for each drug identified by National Drug Code ("NDC"). There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWPs for the tens of thousands of drugs. These compendia have generally been published by: (1) Thompson Publishing, publisher of the *Red Book* and various other price publications; (2) First Databank, publisher of the *Blue Book* and other electronic price publications; or (3) Medi-Span, Inc., publisher of an electronic or automated price service and the Hospital Formulary Pricing guide. Thompson Publishing, First Databank and Medi-Span, Inc. are hereafter referred to as the "Publishers" and their various publications and data services are hereinafter referred to as "Price Publications."

56. In periodically announcing the AWP and WAC for each drug, the Publishers publish the prices that are supplied to them by pharmaceutical manufacturers for their respective drugs. The forward to the 1999 edition of the RedBook states that "all pricing information is supplied and verified by the products manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted." A June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the RedBook, stated that it only publishes prices that are faxed directly from the manufacturer. Thus, the AWP and WAC generally are not

independently determined by the Publishers. The pharmaceutical manufacturers control the prices listed as the AWPs and WACs for each drug.

57. The Medicaid system, which bases its reimbursement rates for drugs on the published AWP and WAC, is thus dependent on the honesty of the drug manufacturers.

58. Settlements and extensive and ongoing federal and Congressional investigations have revealed that numerous pharmaceutical manufacturers have engaged in a scheme involving the fraudulent reporting of the AWPs for certain prescription pharmaceuticals including, but not limited to, prescription pharmaceuticals covered by Medicaid.

b. Multi-Source Drug Reimbursement

59. States use either maximum allowable cost ("MAC") or the federal upper limit ("FUL") to determine Medicaid reimbursement for multiple source drugs. States with a MAC system either use the lowest AWP for a generic version of the drug or their own formulas to determine MAC. States with MAC programs generally publish lists of generic and multi-source drugs along with the maximum price at which Medicaid will reimburse. In general, the prices on the MAC lists are lower than the FUL prices set by the federal government.

60. Some states instead rely on the FULs to set reimbursement for multiple source drugs. The federal government sets FUL on multiple source drugs that are available from at least three suppliers and for which all formulations of the drug are therapeutically or pharmaceutically equivalent. 42 U.S.C. § 1396r-8(e)(4); 42 C.F.R. § 447.332(a). The FUL is set at 150% of the published price for the least costly therapeutic equivalent. 42 C.F.R. § 447.332(b).

c. Other State Methods for Setting Medicaid Reimbursement Rate for Drugs

61. In addition to relying on the manufacturers' reported prices as published in the Price Publications or on MAC or FUL for multi-source drugs, some state Medicaid programs also received price representations directly from manufacturers, and relied on these representations to confirm the accuracy of the figures they use to determine state reimbursement amounts. For example, the State of Texas requires drug companies to submit their prices directly to the Texas Medicaid program in a signed certification attesting to the accuracy of the price information.

iii. "Best Price"

62. There is another aspect to the Medicaid statutory background implicated here. Under 42 U.S.C. § 1396r-8, in order for a manufacturer of a drug to have its products compensated under Medicaid, the manufacturer must enter into a rebate agreement with the Secretary of HHS. Pursuant to the rebate agreement, the manufacturer promises to report to Medicaid its "best price" and to pay rebates to Medicaid to ensure that the nation's insurance program for the poor receives the same favorable drug prices offered to other large purchasers of drugs. The statute defines the best price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity." 42 U.S.C. § 1396r-8(c)(1)(C). The section also provides that "best price" includes "cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates" and does not include "prices that are merely nominal in amount" unless those nominal priced sales are contingent upon any purchase requirement. 42 U.S.C. § 1396r-8(c)(1)(C)(ii).

63. Organon entered into such a rebate agreement with the Secretary of Health and Human Services. In that agreement, Organon agreed to comply with Section § 1396r-8, and hence:

(a) Agreed to report its best price, including cash discounts, free goods contingent upon any purchase requirements, and volume discounts and rebates, in any quarter and to make rebates where necessary; and

(b) Agreed that the best price would not take into account nominal prices, defined as prices that are less than 10% of the average manufacturer's price in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.

64. Many states expressly incorporate the rebate requirements found in 42 U.S.C. § 1396r-8 into their state laws and provide that, when a manufacturer has entered into a rebate agreement, as outlined above, Medicaid reimbursements shall be made only pursuant to the terms of that rebate agreement.

65. Non-compliance with the best price requirements carries strict penalties. For example, 42 U.S.C. § 1396r-8(c)(ii) expressly provides that "any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information."

66. The state Medicaid programs were intended third-party beneficiaries of these rebate agreements.

67. Under the rebate agreement that Organon was required to sign pursuant to 42 U.S.C. § 1396r-8, Organon must report its average manufacturer price ("AMP") and best price for its drugs to Centers for Medicare and Medicaid Services ("CMS") each quarter. The AMP is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary

prompt pay discounts." 42 U.S.C. § 1396r-8(k)(1). Discounts and rebates provided to long-term care pharmacy providers were a customary deduction from AMP during the relevant time period.

68. Best price means the lowest price available from the manufacturer during the rebate period to any wholesaler or provider. *See* 42 U.S.C. § 1396r-8(c)(2)(B). When determining the best price, manufacturers must include cash discounts, free goods, volume discounts, and rebates given on the covered drug. 42 U.S.C. § 1396r-8(c)(1)(C).

69. The amount of the rebate to the state Medicaid programs is calculated in three steps. First, the basic rebate is determined. The basic rebate is equal to the greater of AMP multiplied by 15.1% or AMP minus best price.

70. Second, once the basic rebate has been calculated, any additional rebates are calculated by comparing the current quarter AMP to the baseline AMP. The baseline AMP is defined as the AMP at the time of launch. The difference between the current quarter AMP and the baseline AMP is compared to the Consumer Price Index ("CPI") to determine if the AMP rose at a rate higher than the prevailing CPI. The CPI represents changes in prices of all goods and services purchased for consumption by urban households. If the current quarter AMP exceeds the baseline AMP plus the CPI, the excess amount becomes the additional rebate. If the current quarter AMP is equal to or less than the baseline AMP plus the CPI, there is no additional rebate.

71. Finally, a calculation is performed for the unit rebate amount ("URA") for each NDC of a covered drug. The basic rebate is added to the additional rebate, and then the rebates are divided by the per unit amount of the drug. The resulting number is the URA, which is multiplied by the number of units dispensed to Medicaid recipients under each state participating program.

E. Organon's Scheme to Defraud Medicaid

i. Overview of the Scheme

72. From 1999 through 2005, Organon engaged in a fraudulent scheme designed to exploit the Medicaid reimbursement system by offering profits based on the spread and by offering deep discounts to further increase the spread in exchange for prescriptions for Remeron Tablet and Remeron SolTab at the expense of the state Medicaid programs. Organon's scheme was three-fold. First, knowing that state Medicaid programs relied on Organon's reported prices in the price reporting compendia to set their reimbursement rates for Remeron Tablet and Remeron SolTab, Organon reported inflated AWPs for Remeron Tablet and Remeron SolTab.

73. Organon then increased and marketed this spread by offering deep discounts and rebates to its GPO and individual long-term care pharmacy provider customers. Organon conspired with its customers to increase this spread by entering into long-term contracts with provisions offering excessive and illegal discounts and rebates. These contracts offered a ramp-up discount period whereby the highest levels of discounts were offered temporarily without meeting any market share or volume criteria. This ramp-up discount period started in February of 1999 and was intended to run only through June 1999; through various amendments, however, this ramp-up period was extended for years until it ultimately expired in December 31, 2005. All of these spread enhancements were at Medicaid's expense.

74. Further, Organon was required to calculate its AMP by averaging its actual prices for Remeron Tablet and Remeron SolTab. In making this calculation, Organon made sure to factor in the deep discounts that it illegally offered to pharmacies on these drugs. Doing so produced a lower AMP than if the discounts had not been considered. Under the formula used to calculate a pharmaceutical manufacturer's rebate liability, a reduced AMP results in a lower

rebate amount due Medicaid.[2] Organon therefore decreased its liability under its rebate agreement with Medicaid by including illegally-discounted long-term care prices in its calculation of AMP.

75. In addition, Organon avoided reporting its true best price for Remeron Tablet and Remeron SolTab. For example, in at least two instances, one involving Omnicare and one involving PharMerica, and product with a short-shelf life, Organon avoided disclosing the true best price by coupling the sale of nominally-priced Remeron SolTab with the requirement to purchase a similar quantity at normal commercial prices.

76. Organon's scheme succeeded precisely because providers were able to obtain Remeron Tablet and Remeron SolTab at prices significantly below Medicaid reimbursement levels. The widely-available prices from wholesalers and through GPO agreements for Remeron Tablet and Remeron SolTab drugs were considerably less than the WAC and 44% to 48% less than the reported AWP used to establish the Medicaid reimbursement.

ii. Organon Marketed the "Spread" and Offered Deep Discounts and Other Financial Inducements to Pharmacy Providers

77. Until 1999, Organon negotiated only modest discounts with GPOs–2% to 3% administrative fees paid to the GPO based on members' Remeron purchases, in exchange for promoting the drug to members. These discounts fell under a limited Anti-Kickback Statute exemption for small, fixed GPO discounts. *See* 42 U.S.C. § 1320a-7b(b)(3); 42 C.F.R. § 1001.952(j).

78. Similarly, Organon negotiated contracts for discounted Remeron with major individual long-term care pharmacy providers, but offered only modest discounts. While

[2] A reduced AMP does not, however, affect in any way Medicaid's determination of reimbursement amount for a prescription. In no way, therefore, did calculating a lower AMP constitute a reporting of the discounts to Medicaid. Nor would Medicaid have had any knowledge of the illegal discounts based on this reporting.

Relators have found pre-1999 Remeron pricing contracts to be scarce, at least one contract relating to other drugs during this period reminded both parties of their Medicaid reporting obligations, referencing the Anti-Kickback Statute and regulations that hold that any discount offered to a pharmacy provider is considered illegal remuneration under the Anti-Kickback Statute unless it is reported upon request by the Secretary of HHS or a state Medicaid agency.

79. That contract term appears nowhere in Organon's Remeron contracts after 1998. Moreover, by 1999, while GPOs' modest "administrative fee" was still in place, Organon had begun offering much larger discounts and rebates of various kinds, particularly to pharmacy providers operating in long-term care. As Remeron SolTab was launched in the hopes of maintaining Organon's Remeron market share in the face of generic competitors, and anxiety rose among Remeron managers, the company's culture increasingly supported a willingness to preserve Remeron business, whatever the means.

80. During this period, Carroll "Butch" McKenna, Director for Senior Care/Long Term Care, and John Maddox, Manager for Senior Care/Long Term Care, within the National Accounts Division, handled all the contracting with the large long-term care chains and pharmacy managers. McKenna later disclosed to Relator Banigan in private conversation that, beginning in 1999, Remeron Tablet sales were driven in large part by discounts and marketing long-term care pharmacy providers' ability to profit. McKenna's newly-assembled Long Term Care sales team promoted Remeron Tablet and later Remeron SolTab almost exclusively by selling the products' relative margin and spread. The sales team used various tools to help them describe a customer's opportunity to profit, including a price calculator to calculate or compare products' relative spread.

81. According to McKenna, in the early part of 2002, about one year before generic Remeron arrived on the market, Organon Long-Term Care staff and their pharmacy provider customers focused increasingly on preservation of pharmacists' Remeron profit opportunities upon the arrival of generic competition. Long-term care field sales representatives discussed with long-term care pharmacy providers the effects on Medicaid reimbursements when multiple generics enter the market. Organon's pitch, as described by McKenna, was:

> Multiple generics are on the horizon for Remeron Tablets. It is likely that six months post launch of the first generic, you will encounter a Medicaid-imposed "MAC" (maximum allowable cost) on both Remeron Tablets and its generic counterpart. Once that happens your profits will go into the crapper, so it is better to transition over to branded Remeron SolTab where you will not be subject to payment limitations that are referenced against generics. Stick with the brand for long-term profitability.

82. McKenna and his Long-Term Care sales team reminded customers that after generic Desyrel (trazadone) and generic Prozac (fluoxetine) became available, LTC pharmacies actually lost money on those scripts. The same fate, they warned, awaited the pharmacies with regard to Remeron if they did not transition over to patent-protected Remeron SolTab. Organon's long-term care customers were often astute enough to check the "orange book" to confirm that Remeron SolTab was not AB-rated against Remeron Tablet, and thus the drug still had protection from generic competition.

iii. Marketing Strategies and Tools

a. 2001 Business Plan for Selling Remeron to Long-Term Care

83. Organon's scheme to market profits to long-term care pharmacists at Medicaid's expense is reflected in an internal 2001 business plan. In early 2001, just as Remeron SolTab was launched, McKenna and Maddox, eager to convert Remeron Tablet market share in the Long Term Care segment to Remeron SolTab, created a "Business/Strategic Plan" ("Business

Plan"). That plan described Remeron's long-term care market share, main competitors, and main customers, discussed Medicaid as the major payor in this segment, and set the goal of converting 60% of Remeron prescriptions in the long-term care segment to Remeron SolTab by April 1, 2002, while simultaneously increasing overall Remeron sales by 20%. The Business Plan laid out charts listing specific strategies for accomplishing those goals with regard to major customers Omnicare, PharMerica, NeighborCare, NCS Healthcare, Sunscript, Owen, MHA, and GeriMed.

84. The Business Plan reveals that Organon long-term care managers were aware that Medicaid paid for most Remeron prescriptions in that area of health care, and purposefully marketed to pharmacies the profits to be made from Medicaid reimbursement at Medicaid's expense. The Business Plan noted, for instance:

> States are undergoing major changes in Medicaid reimbursement which can affect Remeron SolTab sales. Contract strategy may need changing due to states going from AWP to Acquisition costs.

This aspect of the business plan coincided with Organon's shift to off-invoice rebates, as described in more detail below.

85. In addition, the Business Plan named as one strategy to implement that Organon LTC sales representatives be trained to use a "Profit Calculator," presumably to show pharmacies their potential profit from Remeron scripts. Further, the Business Plan demonstrates the involvement in the Medicaid scheme of high-level Organon management and teams including Legal and Contract Development, all to be repeatedly consulted in developing strategies for selling Remeron to long-term care pharmacies.

86. Another strategy proposed in the Business Plan was the creation of materials to assist long-term care pharmacies to implement a "therapeutic interchange" to authorize the

conversion of Remeron Tablet prescriptions and other prescriptions to Remeron SolTab. The proof that Organon management did indeed approve McKenna's and Maddox's business plan is the finished therapeutic interchange "Toolkit" itself, which is described below.

b. 2002 Marketing Strategy Presentation

87. A 2002 Marketing Strategy Presentation depicted Organon's scheme to market profits to long-term care pharmacists at Medicaid's expense and Organon's goal of converting prescriptions from Remeron Tablet to Remeron SolTab. In 2002, Gail Sibert, Senior Product Manager of National Accounts for Organon, presented a PowerPoint presentation entitled "Strategy & Tactics to Mitigate Potential Share Erosion of RemeronSolTab® Subsequent to the Launch of Generic Mirtazapine" (hereafter the "2002 Marketing Strategy Presentation"). The 2002 Marketing Strategy Presentation stated: "Shifting the franchise to RemeronSolTab is the cornerstone of the 2002 marketing strategy, and thus maintaining RemeronSolTab share of the total mirtazapine market subsequent to the launch of generic mirtazapine is imperative." The 2002 Marketing Strategy Presentation continued, "[a]s of May 24 (2002), Organon shifted 28% of its Remeron Tablet franchise to RemeronSolTab. RemeronSolTab conversion continues to grow by about 1-2% monthly, and we anticipate this rate to increase as more LTC providers adopt and comply with the new contract strategy."

88. The 2002 Marketing Strategy Presentation elaborated that the core strategy for the 2002 Remeron marketing campaign was to: "[d]evelop and deliver strong 'no substitution' messages to key segments to aggressively manage the rate of conversion subsequent to the launch of generic mirtazapine. Target state boards of pharmacy, key retail institutions, LTC and Medicaid."